SEP 2 1 2005

Special 510(k) Summary of Safety and Effectiveness:
Line Extension to the OASYS™ System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person:	Simona Voic Regulatory Affairs Project Manager
Date of Summary Preparation:	August 24, 2005

Device Identification

Proprietary Name:	Stryker Spine OASYS™ System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 Pedicle Screw Spinal System 21 CFR §888.3070

Predicate Device Information: K032394 Stryker Spine OASYS® System

The Stryker Spine OASYS™ System is comprised of rods, polyaxial screws, bone screws, hooks, connectors, and an occiput plate. The components are available in a variety of lengths in order to accommodate patient anatomy. The components are fabricated from Titanium alloy and are provided non-sterile. The Stryker Spine OASYS™ System can be linked to the Stryker Spine Xia® Spinal System via the rod-to-rod connectors.

Description of Device Modification

This submission is intended to address a line extension to Stryker Spine OASYS™ System. The line extension includes a new range of Titanium alloy axial & parallel rod-to-rod connectors, standard hooks & rods as well as new CP Titanium rods. The new range of Titanium alloy axial and parallel rod-to-rod connectors will also facilitate the linkage between Stryker Spine OASYS™ and SR90D Systems.

Indication for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3), the Stryker Spine OASYS™ System is intended for:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Atlanto/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Intended Use:

The Stryker Spine OASYS™ System can be linked to the Xia Spinal System and SR90D System via the rod-to-rod connectors.

Statement of Technological Comparison:

The subject components share the same indications for use, material, and basic design concepts as that of the predicate device: Stryker Spine OASYS™ System (K032394). Mechanical testing also demonstrated comparable mechanical properties to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Ms. Simona Voic
Regulatory Affairs Project Manager
Stryker Spine
2 Pearl Court
Allendale, NJ 07401

Re: K052317
Trade Name: Stryker Spine OASYS™ System (Line Extension)
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP, MNI
Dated: August 24, 2005
Received: August 25, 2005

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052317

Device Name: Stryker Spine OASYS™ System

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The Stryker Spine Oasys System can be linked to the Xia Spinal System and SR90D System via the rod-to-rod connectors.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052317